15-1195

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), *see* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21, created a new regulatory pathway, 42 U.S.C. § 262(k), by which the FDA could approve a biologic product as "biosimilar to" a "reference product" that was itself approved under the full, traditional pathway of 42 U.S.C. § 262(a). "[B]alancing innovation and consumer interests," Pub. L. No. 111-148 § 7001(b), Congress established procedures to control and streamline patent litigation between the biosimilar applicant (the "Applicant") and the reference product sponsor (the "Sponsor" or "RPS"), *see* 42 U.S.C. § 262(*l*), triggered by the filing of an application under the new abbreviated pathway, *see id.* § 262(*l*)(1)(B)(i).

Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") respectfully file this Conditional Cross-Petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit regarding its interpretation of one part of the integrated patent-litigation procedures in subsection 262(*l*). Specifically, subparagraph 262(*l*)(2)(A) requires that, within 20 days of the FDA accepting its biologics license application for review under the new, abbreviated regulatory pathway, the Applicant "shall provide" the Sponsor with a copy of that biologics license application and related information about the manufacture of its proposed biosimilar product. Despite the statute's use of the mandatory verb "shall" and the centrality of the biologics

QUESTION PRESENTED (CONTINUED)

license application and manufacturing information to many of the steps of the patent-dispute-resolution procedures, the Federal Circuit held that an Applicant is not required to provide that information to the Sponsor and that a court cannot compel an Applicant to provide that information.

The question presented by this Conditional Cross-Petition is:

> Is an Applicant required by 42 U.S.C. § 262(*l*)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?

Cross-Respondent Sandoz Inc. ("Sandoz") has already filed a petition ("Sandoz's Petition"), which has been docketed as No. 15-1039, asking for this Court to review the Federal Circuit's interpretation of another component of the patent-dispute-resolution procedures of subsection 262(*l*), the notice of commercial marketing required by subparagraph 262(*l*)(8)(A). There, consistent with this Court's statutory-interpretation precedent, the Federal Circuit held that the verb "shall" is mandatory. Notably, Sandoz argues in its petition

QUESTION PRESENTED (CONTINUED)

that subparagraph 262(*l*)(8)(A) is directly connected with the other patent-dispute-resolution procedures of subsection 262(*l*), and ascribes error to the Federal Circuit for "erroneously divorc[ing] the notice of commercial marketing provision from the patent resolution scheme." (Pet. at 31.) For the reasons set forth in Amgen's brief in opposition, the Court should deny Sandoz's Petition. If the Court does so, it should deny this Conditional Cross-Petition too. If, however, the Court grants Sandoz's Petition, it should consider both questions regarding the patent-resolution scheme of the BPCIA by granting this Conditional Cross-Petition as well.

PARTIES TO THE PROCEEDINGS

The caption identifies all parties. Cross-Petitioners are Amgen Inc. and Amgen Manufacturing Limited. Cross-Respondent is Sandoz Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Cross-Petitioners Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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OPINIONS BELOW

The opinion of the Federal Circuit is reported at 794 F.3d 1347 and is reproduced at pages 1a-55a of the Appendix to Sandoz's Petition in 15-1039 ("Pet. App."). The opinion of the district court is unreported but is available at 2015 WL 1264756 and reproduced at Pet. App. 56a-84a. Pursuant to Supreme Court Rule 12, Amgen has not reproduced the materials included in the Appendix to Sandoz's Petition.

JURISDICTION

The Federal Circuit entered judgment on July 1, 2015. Amgen and Sandoz each petitioned for rehearing en banc, and those petitions were denied on October 16, 2015. (Pet. App. at 85a-86a.) On December 29, 2015, the Chief Justice extended the time for Sandoz to petition for a writ of certiorari to and including February 16, 2016. Sandoz filed its petition for a writ of certiorari, No. 15-1039, on that day, and it was docketed on February 18, 2016. This Conditional Cross-Petition is timely pursuant to this Court's Rule 12.5. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The BPCIA, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), and the relevant provisions of Titles 28, 35, and 42 of the United States Code amended by the BPCIA are reprinted at Pet. App. 87a-163a. Paragraph 262(*l*)(2) of Title 42 provides:

STATUTORY PROVISIONS INVOLVED (CONTINUED)

(2) Subsection (k) application information. Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

INTRODUCTION

The Federal Circuit's decision in this case was its first significant analysis of the "patent-dispute-resolution regime" of the BPCIA. (Pet. App. at 6a (citing 42 U.S.C. § 262(*l*).). Subsection 262(*l*) creates "a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes." (*Id.*)

The Federal Circuit panel considered two components of that elaborate process, construing one of them as Sandoz had proposed and one of them as Amgen had proposed. These are those components:

Provision of the aBLA Under § 262(*l*)(2)(A): The patent procedures of subsection 262(*l*) commence as soon as the Applicant chooses to file an abbreviated biologics license application ("aBLA" or "subsection (k) application") under the subsection (k) pathway, rather than a full application under the traditional subsection (a) pathway. *See* 42 U.S.C. § 262(*l*)(1)(B)(i). An Applicant that chooses to avail itself of the benefits of the subsection (k) pathway—including referencing the Sponsor's license and clinical trial data—must provide to the Sponsor the information that is the foundation of the exchange procedures:

> When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the [Sponsor], subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to

> paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

42 U.S.C. § 262(*l*)(1)(B)(i). The reference to "paragraph (2)" is to the provision at issue on this Conditional Cross-Petition, which requires the Applicant to give the Sponsor a copy of its aBLA and other information about the manufacture of its proposed biosimilar product within 20 days of being notified that the FDA has accepted its application for review:

> (2) Subsection (k) application information. Not later than 20 days after the [FDA] notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—
>
> (A) shall provide to the reference product sponsor a copy of the application submitted to the [FDA] under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

42 U.S.C. § 262(*l*)(2)(A), (B) (emphasis added).

The Federal Circuit interpreted the verb "shall" in subparagraph 262(*l*)(2)(A) not to be mandatory, holding, over a dissent by Judge Newman, that the BPCIA explicitly contemplates that an Applicant need not provide the Sponsor with a copy of its aBLA and manufacturing information, and that where an Applicant refuses to provide this information the Sponsor's sole remedy is to sue for a declaratory judgment under 42 U.S.C. § 262(*l*)(9)(C) or for patent infringement under 35 U.S.C. § 271(e)(2)(C)(ii), limited to the remedies in 35 U.S.C. § 271(e)(4). (Pet. App. at 15a-18a.) The Court held that Sandoz's refusal to provide Amgen with a copy of Sandoz's aBLA and manufacturing information under subparagraph 262(*l*)(2)(A) was not a violation of the BPCIA sufficient to support an injunction under Amgen's California state-law claims. (Pet. App. at 27a-29a.)

The Federal Circuit reached this holding despite this Court's clear precedent that the verb "shall" ordinarily signifies a mandatory command, a meaning that is reinforced where—as here—the "shall" command is juxtaposed against the permissive "may." *See, e.g., Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895). And by allowing the Applicant to refuse to provide its aBLA and manufacturing information, the Federal Circuit allowed the Applicant to prevent the later steps of the elaborate process that depend on the provision of that information, including paragraphs 262(*l*)(3), (4), and (5), and to prevent the filing of the "Immediate

patent infringement action" under paragraph 262(*l*)(6) that Congress intended to end the first phase of dispute resolution under the BPCIA. Here, too, Judge Newman dissented. (Pet. App. at 35a-42a.)

180 Days' Notice Under § 262(*l*)(8)(A): The second phase of dispute resolution begins when the FDA approves the Applicant's aBLA. *See* 42 U.S.C. § 262(*l*)(8). The statute requires the Applicant then to give at least 180 days' notice to the Sponsor of the date on which it will commence commercial marketing, in order to give the Sponsor time to bring, and the courts time to address, preliminary-injunction motions, including on patents that issue after the exchange of information leading to the paragraph 262(*l*)(6) lawsuit or were otherwise not listed for inclusion in that lawsuit. *See id.* § 262(*l*)(7), (8)(A), (8)(B). Thus, the statute provides that "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." *Id.* § 262(*l*)(8)(A).

The Federal Circuit unanimously held, based on Congress's unique use here of the phrase "the biological product licensed" and on the statutory context, that notice of commercial marketing is effective only if given after FDA approval. (Pet. App. at 19a-22a.) And the Federal Circuit then held, in this regard over a dissent by Judge Chen, that the word "shall" in subparagraph 262(*l*)(8)(A) is mandatory. (Pet. App. at 23a-26a.)

Sandoz's Petition challenges the Federal Circuit's unanimous holding that effective notice may be given only after FDA approval. (*See* Pet. at ii.) And while Sandoz gave notice after FDA approval, committing to wait 180 days from then to begin commercial marketing, Sandoz now challenges as error the Federal Circuit's continuation of an injunction pending appeal to prohibit Sandoz from beginning commercial marketing in the 180-day period when it promised not to do so anyway. (*See* Pet. at 31.)

For the reasons set forth in Amgen's brief in opposition to Sandoz's Petition, the Court should deny Sandoz's Petition. To date there have been only seven lawsuits involving a biosimilar applicant's submission of an abbreviated biologics license application ("aBLA") to the FDA. All are still pending, and they present questions not only of underlying patent-law issues—whether a given product infringes a given patent, and the like—but also questions about how the BPCIA patent-litigation procedures are to be construed and applied. The Federal Circuit will hear oral argument on April 4, 2016 in a case about the very provision Sandoz would have this Court construe. *See Amgen Inc. v. Apotex Inc.*, No. 2016-1308 (Fed. Cir. appeal docketed Dec. 11, 2015) (addressing whether notice under subparagraph 262(*l*)(8)(A) is mandatory for an Applicant that provides its aBLA under subparagraph 262(*l*)(2)(A)).

If, however, this Court grants Sandoz's Petition, it should grant this Conditional Cross-Petition as well, to review the Federal Circuit majority's conclusion that the Applicant does not need to do

what subparagraph 262(*l*)(2)(A) says it "shall" do: provide the Sponsor with a copy of its aBLA and related manufacturing information. The Court should take up both issues if it takes up either, for these reasons:

First, the issues are inextricably intertwined. Both provisions are triggered by the Applicant's choice to seek FDA licensure under the subsection (k) pathway, rather than the traditional approval pathway. *See* 42 U.S.C. § 262(*l*)(1). And both provisions say that the Applicant "shall" do certain tasks, *see id.* § 262(*l*)(2)(A), (8)(A), yet differently composed majorities of the Federal Circuit construed one "shall" as mandatory and one, in effect, as optional. (*See* Pet. App. at 15a, 23a.) The Court should consider the meaning of both provisions if it considers the meaning of either.

Second, the Federal Circuit majority's decision that the "shall" in subparagraph 262(*l*)(2)(A) is optional conflicts with controlling precedent from this Court, including cases holding the verb "shall" is ordinarily mandatory, and is clearly mandatory where, as here, it is juxtaposed with the verb "may." *See, e.g., Nat'l Ass'n of Home Builders*, 551 U.S. at 661-62; *Jama v. Immigration & Customs Enf't*, 543 U.S. 335, 346 (2005); *Lopez*, 531 U.S. at 241; *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947); *Thoman*, 156 U.S. at 359-60. The Federal Circuit majority's conclusion is also at odds with the larger statutory text, which at least four times refers to provision of the aBLA and manufacturing information as "required," and twice refers to an Applicant's non-provision of that information as a "fail[ure]." *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A),

(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). The Federal Circuit majority's conclusion that an Applicant may simply refuse to participate in the threshold step of the procedures of subsection 262(*l*) destroys the balance the BPCIA sought to create between innovation and price competition, tipping that balance in favor of the Applicant. So, too, does the Federal Circuit majority's conclusion that, where an Applicant refuses to provide the information required by subparagraph 262(*l*)(2)(A), the Sponsor's sole remedy is to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii), limited to the remedies set forth in § 271(e)(4).

If the Court grants Sandoz's Petition to review another aspect of subsection 262(*l*) that is triggered by the filing of a subsection (k) application, it should grant Amgen's Conditional Cross-Petition as well.

STATEMENT OF THE CASE

A. The Biologics Price Competition and Innovation Act of 2009

Congress enacted the BPCIA as part of the Patient Protection and Affordable Care Act, because it was "the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." Pub. L. No. 111-148, § 7001(b). Its goal was to allow for the regulation and licensure of potentially-lower-cost biosimilar products, while protecting the value to society of innovators' patent rights.

Before the BPCIA was enacted, the FDA could approve a biologics license application only under the full biologics pathway of 42 U.S.C. § 262(a), with its usual requirement of three phases of clinical trials to prove that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). An innovator of a new biological product was assured that, even apart from whatever patent protection it might have on that product, no other company could copy that biological product and obtain FDA approval without first undergoing the expense of the 262(a) pathway. The innovator's investment to create a clinical trial data package to support and maintain FDA licensure of the innovator's biologic product was thereby protected from use, without the innovator's permission, by or for the benefit of would-be competitors.

The BPCIA changed that. Congress created a new biosimilars approval pathway, codified in 42

U.S.C. § 262(k) and commonly called "the (k) pathway." It allows the FDA to approve a biologic product that is "highly similar" to a "reference product" that was itself previously approved under the traditional subsection 262(a) pathway. *See id.* § 262(i)(2), (k)(3). Thus, while innovators previously enjoyed permanent and exclusive rights to their clinical trial data and FDA license, and reference to an innovator's biological license could be made only with permission from the innovator, the BPCIA advanced the public's interest in price competition in part by diminishing these innovators' rights. It allowed an Applicant to "reference" the innovator's license, and to demonstrate that its proposed product is "highly similar" to the innovator's "reference product," *id.* § 262(i)(2), (k)(3), rather than incurring the costs of generating its own clinical data to demonstrate safety and efficacy. The BPCIA has no grandfather provision that would limit its applicability to only reference products licensed after the effective date of the legislation. *See id.* § 262(k).

On the other side of the balance, Congress protected the public's interest in innovation by establishing in subsection 262(*l*), "Patents," what the Federal Circuit aptly termed a "unique and elaborate process for information exchange between the biosimilar applicant and the [Sponsor] to resolve patent disputes." (Pet. App. at 6a.) The process begins when the Applicant files an aBLA seeking review under the subsection (k) pathway. *See* 42 *U.S.C.* § 262(*l*)(1)(B)(i).

The provision at issue on this Conditional Cross-Petition, paragraph 262(*l*)(2), states:

> (2) Subsection (k) application information. Not later than 20 days after the [FDA] notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—
>
> (A) shall provide to the reference product sponsor a copy of the application submitted to the [FDA] under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

Id. § 262(*l*)(2). The Sponsor then uses the Applicant's aBLA and manufacturing information to identify patents that the Sponsor believes could be infringed by the making, using, selling, offering for sale, or importing of the Applicant's proposed biosimilar product. Paragraph 262(*l*)(3) requires the Sponsor to identify those patents, and requires the Applicant and the Sponsor to exchange detailed infringement and invalidity contentions and to address licensure under some or all of those patents, and requires the Applicant to state whether it will await the expiry of some or all of those patents before marketing its product. *See id.* § 262(*l*)(3)(A), (B), (C). If there remain patents in dispute, the Sponsor and Applicant work together to identify which of those patents will be included in an "Immediate patent infringement action" under paragraph 262(*l*)(6). *See id.* § 262(*l*)(4), (5), (6).

The reason that the lawsuit in paragraph 262(*l*)(6) is called an "immediate" patent infringement action is that it represents the conclusion of the first of two phases under subsection 262(*l*). The second phase begins with the FDA's approval of the Applicant's biosimilar application. *See id.* § 262(*l*)(8). Because the BPCIA permits the submission of a biosimilar application four years after approval of the reference product, *id.* § 262(k)(7)(B), but prohibits licensure of the biosimilar product until twelve years after that date, *id.* § 262(k)(7)(A), the two phases of litigation may be separated by a period of several years.

FDA licensure of the biosimilar product authorizes the Applicant to commercially market the biosimilar in the United States. *See id.* § 262(a)(1)(A). It also triggers the Applicant's obligation to give the Sponsor at least 180 days' advance notice of the date of the first commercial marketing of the licensed biosimilar product. *See id.* § 262(*l*)(8)(A). (This is the provision addressed by Sandoz's Petition.) This allows the Sponsor an opportunity to seek a preliminary injunction prior to the commercial marketing of the approved product, including on the patents identified in subparagraph 262(*l*)(8)(B).

The final part of subsection 262(*l*), paragraph 262(*l*)(9), is entitled "Limitation on declaratory judgment action." In this regard, the BPCIA borrows from the Hatch-Waxman Act (which provides for an abbreviated FDA approval pathway for small-molecule drugs, and patent-dispute-resolution provisions for applicants and sponsors of

such drugs)[1] and prohibits gaming the system by placing limits on any actions for declaratory judgments with respect to patents that do not make the list, pursuant to either paragraph 262(*l*)(4) or 262(*l*)(5), for the immediate patent infringement action under paragraph 262(*l*)(6), plus later-issued or -licensed patents under paragraph 262(*l*)(7). Assuming compliance with the BPCIA patent provisions, that limitation first ends when the Applicant gives the at-least-180-days' advance notice of first commercial marketing of the licensed biosimilar product. Thus, subparagraph 262(*l*)(9)(A) provides:

> (9) Limitation on declaratory judgment action
>
> (A) Subsection (k) application provided—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

Deferring the availability of declaratory-judgment actions until the Applicant provides the

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[1] Drug and Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355, 28 U.S.C. § 2201, and 35 U.S.C. §§ 156, 271, & 282).

notice of commercial marketing benefits both the Applicant and the Sponsor, for example by ensuring that both parties earnestly engage in the first phase of the BPCIA's patent-resolution process and providing clarity that the respective rights of the parties are and will be preserved. If the Applicant fails to complete an action, the limitation on declaratory-judgment actions is maintained with respect to the Applicant but not with respect to the Sponsor:

> (B) Subsequent failure to act by subsection (k) applicant—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> (C) Subsection (k) application not provided—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

Id. § 262(*l*)(9)(B), (C).

B. Factual Background

1. Sandoz's aBLA and its Initial Notice of Commercial Marketing

Amgen discovered, developed, and markets NEUPOGEN® (filgrastim), a genetically engineered biologic protein that stimulates the production of neutrophils, a type of white blood cell. (*See* Pet. App. at 4a, 57a; D. Ct. Dkt. No. 1 at ¶¶ 45-47.) NEUPOGEN® is used, for example, to protect against a condition known as neutropenia, a potentially fatal neutrophil deficiency, induced in cancer patients by chemotherapy. (D. Ct. Dkt. No. 1 at ¶¶ 45-47.) The advent of NEUPOGEN® profoundly changed the treatment of many forms of cancer by greatly reducing deaths from neutropenia.

Sandoz filed an aBLA under the subsection (k) pathway seeking FDA approval of a biosimilar filgrastim product, designating Amgen's NEUPOGEN® as the reference product. (Pet. App. at 8a.) The FDA notified Sandoz it had accepted that aBLA on July 7, 2014. (*Id.*) Later in July, Sandoz informed Amgen that it would not provide Amgen with its aBLA or manufacturing information under subparagraph 42 U.S.C. § 262(*l*)(2)(A), and—purporting to satisfy the notice requirement of subparagraph 262(*l*)(8)(A)—informed Amgen that it would begin commercial marketing immediately upon FDA licensure. (Pet. App. at 8a-9a.) Sandoz said it expected to receive an FDA license some six to twelve months later, in the first half of 2015. (Pet. App. at 8a.)

2. District Court Proceedings, FDA Approval of Sandoz's aBLA, and Sandoz's Second Notice of Commercial Marketing

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of conversion, unlawful competition under California Business & Professions Code § 17200 et seq., and infringement of U.S. Patent 6,162,427. (Pet. App. at 9a.) The district court had subject matter jurisdiction under 28 U.S.C. § 1332, as well as under 28 U.S.C. § 1331 and 1338(a) with respect to Amgen's patent claims and 28 U.S.C. §§ 1367 and 1338(b) with respect to Amgen's state-law claims. Both state-law claims rested on Sandoz's violations of the BPCIA: Amgen alleged that Sandoz had competed unlawfully and converted the value of Amgen's license for NEUPOGEN® by availing itself of the right to reference that license under the BPCIA while refusing to disclose its aBLA and manufacturing information to Amgen under subparagraph 262(*l*)(2)(A) and giving improper notice of commercial marketing under subparagraph § 262(*l*)(8)(A). (*See id.*) Sandoz counterclaimed for declaratory judgments that its reading of the BPCIA was correct. (*Id.*) Amgen sought a preliminary injunction, and the parties cross-moved for judgment on Amgen's state-law claims and Sandoz's counterclaims. (*Id.* at 9a-10a.)

While the motions were pending, on March 6, 2015 the FDA approved Sandoz's aBLA, licensing Sandoz to sell its biosimilar filgrastim product under the name ZARXIO®. (*Id.* at 8a-9a.) That same day, while maintaining that its July 2014 notice of commercial marketing had been operative,

Sandoz gave Amgen a "further" notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*Id.*)

On March 19, 2015, the district court granted partial judgment to Sandoz, holding that (i) despite the use of the words "shall provide," the BPCIA allows an Applicant to refuse to provide its aBLA and manufacturing information; (ii) where an Applicant refuses to provide that information, the Sponsor may not obtain injunctive relief, restitution, or damages for that refusal, and is instead limited to seeking a declaratory judgment under subparagraph § 262(*l*)(9)(C); and, (iii) the Applicant may give notice of commercial marketing under subparagraph 262(*l*)(8)(A) before FDA approval, and thus that Sandoz's July 2014 notice was timely. (*Id.* at 10a.) The district court entered judgment against Amgen on its state law claims, and denied its motion for a preliminary injunction. (*Id.*) Proceedings on Amgen's patent claim were stayed, and Amgen timely appealed to the Federal Circuit. (*Id.* at 11a.)

3. The Federal Circuit Decision

Amgen sought an injunction pending appeal under Fed. R. App. P. 8(a) and the traditional four factors of the equitable test for such an injunction: likelihood of success on the merits, irreparable harm, a balance of hardships favoring the movant, and the public interest. (*See* Pet. App. at 31a; CAFC Dkt. No. 55.) Over Sandoz's opposition, the Federal Circuit entered an injunction pending appeal on May 5, 2015, enjoining Sandoz from marketing, selling, or offering for sale its ZARXIO® product until the court resolved the appeal. (*See*

Pet App. at 31a; CAFC Dkt. No. 83; Order, CAFC Dkt. No. 105 (granting the motion).)

On July 21, 2015, the Federal Circuit issued its decision on Amgen's appeal. (*See* Pet. App. at 1a.) The panel comprised Judges Lourie, Newman, and Chen, with Judge Lourie writing the majority opinion, joined in various parts by Judge Newman and Judge Chen. (*See id.* at 3a.)

Addressing subparagraph 262(*l*)(2)(A), the provision now at issue on this Conditional Cross-Petition, Judge Lourie, joined by Judge Chen, held that while that provision says that the Applicant "shall provide" a copy of its aBLA and related manufacturing information to the Sponsor, that requirement is not actually mandatory, and where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery. (*See id.* at 12a-18a.) Because it found that Sandoz had not violated the BPCIA, the majority affirmed the entry of judgment on Amgen's state-law claims to the extent they were predicated on Sandoz's refusal to provide its aBLA and manufacturing information. (*See id.* at 26a-29a.) Judge Newman dissented from these aspects of the majority's decision. (*See id.* at 35a-42a.)

Turning to the notice of commercial marketing under subparagraph 262(*l*)(8)(A), the Federal Circuit held, unanimously, that such notice is effective only if given after the FDA licenses the product under subsection (k). (*Id.* at 20a-22a.) The

court then considered Sandoz's argument that the "shall" language of subparagraph 262(*l*)(8)(A) is not mandatory and that an Applicant need not provide notice at all. (*Id.* at 23a-26a.) Judge Lourie, joined by Judge Newman, held that an Applicant must give notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*Id.*) Deeming Sandoz's March 6, 2015 notice of commercial marketing to have been "operative and effective" (*id.* at 23a), the majority held that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015" (*id.* at 26a), and extended the injunction pending appeal to only September 2, 2015 (*id.* at 27a-28a, 31a). The majority held that in light of this injunction, "Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot." (*Id.*) Judge Chen dissented from these parts of the panel decision. (*See id.* at 42a-55a.)

Each of Sandoz and Amgen petitioned for en banc review, with Sandoz challenging aspects of the panel's decision regarding notice of commercial marketing under subparagraph 262(*l*)(8)(A) and Amgen challenging the panel's decision regarding the Applicant's obligation to give the Sponsor a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A). (*See* CAFC Dkt. Nos. 118 & 119.) Both petitions for en banc review were denied without further opinion. (Pet. App. at 85a-86a.) Amgen sought to extend the injunction pending appeal while en banc proceedings continued, and that application, too, was denied. (CAFC Dkt. No. 128.) Sandoz began commercial

sales of its ZARXIO® product on September 3, 2015. (Pet. at 20.)

4. Proceedings in This Court

Sandoz filed a petition for a writ of certiorari, No. 15-1039, on February 16, 2016, which was docketed on February 18, 2016.

Sandoz's Petition challenges two aspects of the Federal Circuit's decision: (1) the unanimous holding that the notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) is effective only if given after FDA approval of the biosimilar, and not before; and (2) the extension of an injunction pending appeal through September 2, 2015, which was 180 days after Sandoz's March 6, 2015 notice of commercial marketing. For the reasons set forth in its brief in opposition, Amgen respectfully submits that the Court should deny Sandoz's petition for certiorari.

This Conditional Cross-Petition challenges the Federal Circuit's decision that the language in subparagraph 262(*l*)(2)(A) that the Applicant "shall provide" the Sponsor with a copy of its aBLA and manufacturing information is not mandatory, and that where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery.

If the Court denies Sandoz's Petition, it should deny Amgen's Conditional Cross-Petition as well. If

the Court grants Sandoz's Petition, however, then it should grant this Conditional Cross-Petition too.

REASONS FOR GRANTING THE CONDITIONAL CROSS-PETITION

I. THE COURT SHOULD REVIEW TOGETHER TWO COMPONENTS OF THE SAME INTEGRATED STATUTE, TO WHICH THE FEDERAL CIRCUIT ASSIGNED CONFLICTING MEANINGS DESPITE THEIR IDENTICAL RELEVANT LANGUAGE

Subparagraph 262(*l*)(2)(A) and subparagraph 262(*l*)(8)(A) are each triggered by the Applicant's decision to file an aBLA under the subsection (k) pathway, *see* 42 U.S.C. § 262(*l*)(1)(B)(i), thus availing itself of the Sponsor's clinical trial data package and license, rather than filing under the traditional subsection (a) pathway and needing to generate its own data package. *See generally id.* § 262(k). An Applicant that elects the subsection (k) pathway undertakes concomitant obligations under the patent-dispute-resolution regime of subsection 262(*l*) that protect the public's interest in promoting innovation by safeguarding patent rights. *See id.* § 262(*l*)(1)(B)(i), (*l*)(2)-(8).

Although the first physical act of the process is the provision of the Applicant's aBLA and manufacturing information to the Sponsor, *see* 42 U.S.C. § 262(*l*)(2)(A), the statute commits the Applicant to this process the moment the Applicant chooses the abbreviated regulatory pathway of subsection (k): "When a subsection (k) applicant submits an application under subsection (k), such

applicant shall provide to [the Sponsor] . . . confidential access to the information required to be produced pursuant to paragraph (2)." *See id.* § 262(*l*)(1)(B)(i). The information-exchange provisions of paragraphs 262(*l*)(3), (4), and (5) all depend on the Applicant providing its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), as does the Sponsor's commencement of the immediate patent infringement action under paragraph 262(*l*)(6), and as does the provision for supplementing the previous patent lists with newly-issued or -licensed patents under paragraph 262(*l*)(7). And the notice of commercial marketing required under subparagraph 262(*l*)(8)(A) also is triggered by the Applicant's having chosen the subsection (k) pathway rather than the traditional subsection (a) pathway.

All of these provisions speak in terms of what the Applicant (and, sometimes, the Sponsor) "shall" do. The provisions at issue on Sandoz's Petition and Amgen's Conditional Cross-Petition each state that the Applicant "shall" do something in the BPCIA's patent-dispute-resolution regime. *See* 42 U.S.C. § 262(*l*)(2)(A), (*l*)(8)(A). Yet the Federal Circuit assigned contradictory meanings to identical verbs, holding that one "shall" is mandatory and one is optional. (*Contrast* Pet. App. at 15a ("[S]hall in paragraph (*l*)(2)(A) does not mean 'must.'"), *with id.* at 23a ("A question exists, however, concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is.").) If the Court construes either provision, it should construe both at the same time, and—consistent with the statute's text—construe them as mandatory.

It would cause great confusion to the lower courts and the biopharmaceutical industry if this Court were to decide the meaning of "shall" for only one provision of the statute and not for all of its provisions, or to decide that one "shall" is mandatory but others are not.

Moreover, the provisions of subsection 262(*l*) are connected not only in language but in function. On this, the parties agree. For its part, Sandoz asserts that which of the Applicant or the Sponsor can commence patent litigation, "when, and for what relief depends on the actions or inactions at each step of a multi-step information exchange process between the applicant and the sponsor regarding the sponsor's possible patent claims. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9)." (Pet. at 9.) Indeed, one of Sandoz's bases for seeking certiorari is its criticism that the Federal Circuit wrongly treated subparagraph 262(*l*)(8)(A) as a "standalone" provision, "disconnecting the notice provision from the BPCIA's patent resolution regime." (*Id.* at 22.) While that one subparagraph is not itself tied to any other provision of subsection 262(*l*), and thus while it does stand alone, Sandoz and Amgen agree that the provisions as a whole interrelate with each other in defining the obligations of the Applicant and the Sponsor where an Applicant chooses to avail itself of the subsection (k) pathway.

Therefore, if the Court is to address subparagraph 262(*l*)(8)(A) in Sandoz's Petition, it should address the statutory subsection as a whole, including the Federal Circuit's construction of subparagraph 262(*l*)(2)(A). As Amgen shows below

in Point II, that construction runs afoul of this *Court's statutory-construction precedents*, independently warranting review.

II. THE FEDERAL CIRCUIT'S CONSTRUCTION OF THE VERB "SHALL" IN SUBPARAGRAPH *262(L)(2)(A) CONFLICTS WITH THIS COURT'S* STATUTORY-INTERPRETATION *PRECEDENTS*

A. Congress's Use of "Shall" and "May" Confirms *That "Shall" Is Mandatory*

This Court's precedents instruct that "all statutory construction cases . . . begin with the language of the statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002). Here, Congress used clear language to compel the Applicant to provide its *aBLA and manufacturing information to the* Sponsor:

> (2) Subsection (k) application information. Not later than 20 days after the [FDA] *notifies the subsection (k) applicant that the* application has been accepted for review, the subsection (k) applicant—
>
> (A) shall provide to the reference product *sponsor a copy of the application submitted* to the [FDA] under subsection (k), and such *other information that describes the process* or processes used to manufacture the biological product that is the subject of such application; and

> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

42 U.S.C. § 262(*l*)(2) (emphasis added). The verb "shall," this Court instructs, is generally mandatory. *See, e.g., Nat'l Ass'n of Home Builders*, 551 U.S. at 661-62; *Lopez*, 531 U.S. at 241. And where—as here—"shall" is used in juxtaposition to the word "may," the "shall" is clearly mandatory. *See, e.g., Jama*, 543 U.S. at 346; *Lopez*, 531 U.S. at 241; *Anderson*, 329 U.S. at 485; *Thoman*, 156 U.S. at 359-60. The plain text of subparagraph 262(*l*)(2)(A) requires the Applicant to provide its aBLA and manufacturing information to the Sponsor.

B. The Surrounding Context Confirms That "Shall" Is Mandatory

While the language of subparagraph 262(*l*)(2)(A) is thus itself sufficient to confirm the Applicant's obligation to provide the aBLA and manufacturing information, the BPCIA reinforces this obligation in several other sections.

It does so first by tying an Applicant's choice to access the biosimilar subsection (k) pathway to its providing this information, stating that: "When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide" to the Sponsor "the information required to be produced pursuant to paragraph (2)." 42 U.S.C. § 262(*l*)(1)(B)(i) (emphases added).

The use of the phrase "the information required

to be produced pursuant to paragraph (2)" is not unique to subparagraph 262(*l*)(1)(B)(i). The BPCIA refers to the aBLA and manufacturing information as "required" in three other places, in two of them referring to non-provision of that information as a "failure":

- Subparagraph 262(*l*)(9)(A) begins, "If a subsection (k) applicant provides the application and information required under paragraph (2)(A) . . . ." (emphasis added).

- Subparagraph 262(*l*)(9)(C) begins, "If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A) . . . ." (emphasis added).

- The provisions added to the Patent Act to create a technical act of infringement as part of the BPCIA state, in relevant part, "if the applicant for the application fails to provide the application and information required under section [262](*l*)(2)(A) of" subsection 262(*l*). 35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added).

These provisions further confirm that the Applicant is required to provide its aBLA and manufacturing information to the Sponsor.

C. The Statutory Purpose Confirms That "Shall" Is Mandatory

The statutory purpose also confirms that the Applicant is required to provide its aBLA and manufacturing information to the Sponsor.

As Judge Newman explained in dissent, the BPCIA "ensure[s] that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." (Pet. App. at 35a (emphasis removed).) Among those relevant patents are manufacturing patents, which are particularly important in protecting innovation in the area of biologics. Thus, while the provisions of the Hatch-Waxman statute dealing with patent disputes concerning generic drugs cover only patents on the chemical entity or methods of use, the BPCIA includes manufacturing patents, *see* 42 U.S.C. § 262(*l*)(3), and requires the Applicant to provide "information that describes the process or processes used to manufacture the biological product that is the subject of such application" so the Sponsor can assert those patents. *Id.* § 262(*l*)(2)(A). Without the Applicant's aBLA and manufacturing information, the Sponsor would likely have no way of knowing which, if any, of its manufacturing patents would be infringed by the Applicant's manufacturing processes; those processes are nearly always closely held secrets.

If an Applicant can refuse to provide the required information, it can tip the balance that the BPCIA was intended to create. As Judge Newman observed: "Subsection (k) and subsection (*l*) are components of an integrated framework; to enjoy the benefits of subsection (k), the biosimilar applicant is obligated to comply with subsection (*l*)." (Pet. App. at 40a.) "The consequences of the

majority's ruling are significant," because an Applicant that fails to provide the required information violates the "explicit balance of obligations and benefits" of the BPCIA. (*Id.*)

The risk is particularly acute with respect to the set of remedies Congress created for biosimilar lawsuits. Congress made the filing of an aBLA under the subsection (k) pathway an act of patent infringement, *see* 35 U.S.C. § 271(e)(2)(C), in a way that parallels the treatment of Abbreviated New Drug Applications in the provisions of the Hatch-Waxman Act, *see id.* § 271(e)(2)(A). And Congress created specific remedies for that technical act of infringement in biosimilar cases, including a mandatory permanent injunction:

> [T]he court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

35 U.S.C. § 271(e)(4)(D). Converting to the section numbers as codified, that provision creates a mandatory permanent injunction for infringement

determined in a paragraph 262(*l*)(6) list if the reference product is still within its statutory period of exclusivity under paragraph 262(k)(7). But if the Applicant does not provide its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), then there will never be a paragraph 262(*l*)(6) lawsuit. There may well be litigation between the Applicant and the Sponsor, but it will by definition not be a paragraph 262(*l*)(6) lawsuit. The Applicant will have deprived the Sponsor of the ability to get the mandatory injunction in 35 U.S.C. § 271(e)(4)(D), simply by refusing to provide information the statute says it "shall provide." That upending of the regulatory balance does violence to the statute and to Congress's intent.

To that end, the Congressional record for a prior, rejected piece of biosimilar legislation confirms that the as-enacted provision of subparagraph 262(*l*)(2)(A) is mandatory. As Judge Newman noted in dissent (*see* Pet. App. at 38a), a prior bill, then called H.R. 1427, explicitly included a discretionary, rather than mandatory, patent-exchange procedure. *See, e.g.*, H.R. 1427, 111th Cong. § 3(a)(2)(k)(18)(F) (2009). So did a prior bill in the Senate. *See* S. 623, 110th Cong. § 3(a)(2)(k)(17)(E) (2007) ("Nothing in this paragraph requires an applicant or a prospective applicant to invoke the [patent notification and exchange] procedures set forth in this paragraph."). Neither of these bills passed, however, and the version of the BPCIA that did pass Congress contained the "shall provide" language instead. *See also Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001) ("We ordinarily will not assume that Congress intended to enact

statutory language that it has earlier discarded in favor of other language." (internal quotation marks omitted)).

D. The Federal Circuit Majority Erred in Concluding That "Shall" "Does Not Mean 'Must'"

The Federal Circuit majority (here, Judges Lourie and Chen) initially reached the conclusion that, "read in isolation, the 'shall' provision in paragraph (*l*)(2)(A) appears to mean that a subsection (k) application is required to disclose its aBLA and manufacturing information to the RPS by the deadline specified in the statute." (Pet. App. at 14a.) The majority noted that the BPCIA refers to this information as "required," and focused "[p]articularly" on the language in subparagraph 262(*l*)(1)(B)(i) that provides that an Applicant that "chooses the abbreviated pathway for regulatory approval of its biosimilar product . . . is required to disclose its aBLA and manufacturing information to the RPS." (*Id.* at 14a-15a.) The majority further recognized that the juxtaposition of "shall" and "may" "would appear to indicate that 'shall' signals a requirement." (*Id.* at 15a.)

The majority nevertheless concluded, however, that because of "other provisions" of the BPICA, the "'shall' in paragraph (*l*)(2)(A) does not mean 'must.'" (*Id.*) Specifically, the majority focused on two provisions that the majority concluded, "explicitly contemplate[] that a subsection (k) applicant might fail to disclose the required information by the statutory deadline" and, it found "set[] forth the

consequences for such failure." (*Id.*) Those two provisions are 35 U.S.C. § 271(e)(2)(C)(ii) and 42 U.S.C. § 262(*l*)(9)(C).

Here, the Federal Circuit majority erred. Neither of those provisions provides a remedy for an Applicant's refusal, or purports to limit the available remedies when an Applicant refuses, to provide its aBLA and manufacturing information to the Sponsor.

1. A Declaratory Judgment Under Subparagraph 262(*l*)(9)(C) Is Neither Remedial Nor an Exclusive Remedy

Subparagraph 262(*l*)(9)(C) is part of the "Limitation on Declaratory Judgment Action" imposed by paragraph 262(*l*)(9). Just as the Hatch-Waxman Act contains provisions designed to prohibit gun-jumping through declaratory-judgment actions, the BPCIA contains a prohibition on declaratory-judgment actions designed to last through the first phase of litigation, from the time the Applicant provides its aBLA and manufacturing information to start the information-exchanges that lead to the paragraph 262(*l*)(6) immediate patent infringement action until the FDA approves the aBLA and the Applicant gives 180 days' notice of commercial marketing. Thus, subparagraph 262(*l*)(9)(A) provides:

> (A) Subsection (k) application provided—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference

> product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

42 U.S.C. § 262(*l*)(9)(A). This prohibition on declaratory judgments then persists even where an Applicant fails to comply with the various requirements of subsection 262(*l*), but is lifted for the Sponsor. Subparagraph 262(*l*)(9)(B) continues the declaratory-judgment ban against an Applicant that fails at a later stage of the process, while subparagraph 262(*l*)(9)(C) continues the declaratory-judgment ban against an Applicant that fails to provide its aBLA and manufacturing information:

> (B) Subsequent failure to act by subsection (k) applicant—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> (C) Subsection (k) application not provided—If a subsection (k) applicant fails to provide

> the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

42 U.S.C. § 262(*l*)(9)(B), (C).

Nothing in this paragraph conditions a Sponsor's or the courts' ability to remediate an Applicant's non-compliance with subparagraph 262(*l*)(2)(A) on the Sponsor bringing a declaratory-judgment action. And nothing in this paragraph says that a declaratory-judgment action is a Sponsor's only choice where the Applicant "fails" to provide its aBLA and manufacturing information. All that this paragraph does is prohibit the non-compliant Applicant from bringing certain kinds of declaratory-judgment actions.

As Judge Newman stated, "subsection (*l*)(9)(C) prevents a non-compliant party from obtaining relief through a declaratory judgment action, while that prohibition is lifted as to the aggrieved party." (Pet. App. at 41a.) And its scope is quite limited: it refers to only patents reading on the biological product or its use, not to the important class of manufacturing patents. (*See id.* at 37a-38a; *accord id.* at 16a (majority opinion).) Nothing about the language of this section suggests that it was intended to permit an Applicant to "opt" not to provide its aBLA and manufacturing information, or

that a declaratory-judgment action is the Sponsor's sole remedy where the Applicant—to use the statutory verb and adjective—fails to provide that required information.

2. A Patent-Infringement Suit Under 35 U.S.C. § 271(e)(2)(C)(ii) Is Neither Remedial Nor an Exclusive Remedy

The Federal Circuit majority also cited the technical act of infringement in 35 U.S.C. § 271(e)(2)(C)(ii) as another remedy available to a Sponsor for an Applicant's failure to comply with subparagraph 262(*l*)(2)(A). That provision is also neither remedial nor an exclusive remedy, and is no basis to conclude that "shall" does not mean "must."

As noted above, the BCPIA amended the Patent Act to add a technical act of infringement for biosimilar applications. *See* 35 U.S.C. § 271(e)(2)(C). The act of patent infringement is the submission of the aBLA; which patents are deemed infringed depends on whether the Applicant provides its aBLA and manufacturing information to the Sponsor, and thus whether the Sponsor can use that information to identify applicable patents pursuant to paragraph 262(*l*)(3):

> It shall be an act of infringement to submit—
>
> . . . .
>
> (C)(i) with respect to a patent that is identified in the list of patents described in [42 U.S.C. § 262(*l*)(3)] (including as provided under [42 U.S.C. § 262(*l*)(7)]), an application seeking approval of a biological product, or
>
> (ii) if the applicant for the application fails to provide the application and information required under [42 U.S.C. § 262(*l*)(2)(A)] of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to [42 U.S.C. § 262(*l*)(3)(A)(i)],
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The Federal Circuit majority held that "[u]nder § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to provide the required information under paragraph (*l*)(2)(A) is . . . an act of infringement" (Pet. App. at 16a), and thus that 35 U.S.C. § 271(e)(4) sets forth "the only remedies which may be granted by a court for" that "act of infringement," which do not include an injunction

by the Sponsor to compel statutory compliance (*id* at 18a (emphasis removed)).

That was error. Failing to provide the aBLA and manufacturing information is not an act of infringement. The act of infringement is the submission of the aBLA to the FDA: "It shall be an act of infringement to submit . . . an application seeking approval of a biological product." 35 U.S.C. § 271(e)(2)(C)(ii). The majority reads a limitation into infringement under section 271(e)(2)(C)(ii) that is inconsistent with sections 271(e)(2)(A), (B), and (C)(i)—all of which state that the submission of an application alone shall be an act of infringement. Providing or failing to provide the aBLA and manufacturing information determines the scope of infringement, specifically which patents have been infringed. If the Applicant complies with subparagraph 262(*l*)(2)(A), then submitting its aBLA infringes only the patents identified through exchange in paragraph 262(*l*)(3). If the Applicant fails to provide its aBLA and manufacturing information, then submitting its aBLA infringes any patent that could be identified by the Sponsor during the patent-dispute-resolution regime. Regardless of which patents have been infringed, the remedies provided under section 271(e)(4) are remedies for that infringement and not for a failure to provide the information required under subparagraph 262(*l*)(2)(A).

Where an Applicant fails to provide that information, the Sponsor may sue for patent infringement. But nothing in the BPCIA makes suing for patent infringement the only remedy

available. Indeed, nothing in the BPCIA makes the requirements of 42 U.S.C. § 262(*l*)(2)(A) depend upon the Sponsor's ownership of or license to patents at all.

* * * *

The Federal Circuit majority erred in suggesting that mandating compliance with subparagraph 262(*l*)(2)(A) "would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous." (Pet. App. at 17a.) They are not superfluous. They are among the tools available to a Sponsor where an Applicant refuses to comply with the BPCIA. But nothing about the value of those tools would be undermined by permitting, and nothing about the text or existence of those tools prevents, Sponsors and courts from using broad powers under federal and state laws to remediate the harms to these or, for example, other property rights caused by an Applicant's failure to comply with the BPCIA.

Those harms are not limited to patent infringement. Applicant non-compliance affects the value of innovation, the value of a Sponsor's biologics license, and the value to the court system of an orderly, targeted dispute-resolution regime, and it permits an Applicant to benefit from the subsection 262(k) pathway while denying the Sponsor its rights under subsection 262(*l*). The Federal Circuit majority's decision diminishes the property interest of an innovator like Amgen—which made substantial, risk-based investments, prior to the enactment of the BPCIA, to create a

clinical trial data package and secure and maintain an FDA license for the reference product—by allowing the Applicant to reference that FDA license and clinical trial data without fulfilling its own obligations under the BPCIA and without any means for the Sponsor to compel it to do so. As Judge Newman concluded in dissent, "It is not denied that Sandoz obtained the benefit of the Amgen data in filing under subsection (k). Sandoz should be required to respect its obligations, in fidelity to the statute." (*Id.* at 42a.)

If this Court accepts Sandoz's Petition to review the timing of the obligation in subparagraph 262(*l*)(8)(A) that an Applicant "shall provide" 180 days' notice of commercial marketing, this Court should therefore also grant this Conditional Cross-Petition to review the Federal Circuit's conclusion that in subparagraph 262(*l*)(2)(A) the word "shall" "does not mean 'must'" (*id.* at 15a), and that a Sponsor's sole remedy in the face of Applicant non-compliance is to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii), limited to the remedies in § 271(e)(4). That conclusion is at odds with the Federal Circuit's own treatment of the same word, "shall," in subparagraph 262(*l*)(8)(A), it is at odds with the plain words of the statute, its statutory context, its statutory purpose, and it conflicts with this Court's controlling statutory-construction precedents.

CONCLUSION

This Court should deny Sandoz's Petition in No. 15-1039 for the reasons set forth in Amgen's brief in opposition. But if this Court grants Sandoz's Petition, it should also grant Amgen's Conditional Cross-Petition.

Respectfully submitted,

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